REMARKS

Reconsideration of this application, as amended, is respectfully requested. The Applicants draws the Examiner's attention to the Applicants' related co-pending applications and issued patents (see Appendix B) directed to nanoparticles and methods of preparation and use thereof.

The specification has been amended to update the priority claim. No new matter has been introduced into the application as a result of this amendment.

Claims 1-105 were originally in this patent and were subject to a restriction requirement. The Applicants provisionally elected the invention of Group II (claims 2-24, 29-32, 42, and 43). Non-elected claims were cancelled in order to expedite the prosecution of this application. Claims 2, 23, and 29 were amended to further clarify the invention. New claims 106-121 were added to more fully claim the Applicant's invention. Support for the amendment and new claims can be found in the original claims and originally filed application on page 93, line 17 to page 98, line 23 (Example 5); page 101, line 10 to page 106 (Example 7); page 51, line 23 to page 59, line 3; and Figure 20. Accordingly, no new matter has been introduced into this application as a result of the present amendment to the claims. Claims 1-24, 29-32, 42, 43, and 106-121 are now pending in this case.

Turning to the office action, claims 2, 3-24, 29-32, 42 and 43 were rejected under 35 U.S.C. section 102(e) as being allegedly anticipated by Yguerabide et al. (U.S. Patent No. 6,214,560)("Yguerabide"). The Examiner alleged that Yguerabide disclosed a detection method which employs gold particulate labels for detecting one or more target analytes and thus anticipates the claimed invention. These claims are alternatively rejected as being obvious under 35 U.S.C. section 103(e) as being allegedly obvious over Yguerabide. The applicants respectfully traverse these rejections.

As a general rule, for prior art to anticipate under section 102, every element of the claimed invention must be identically disclosed in a single reference. Corning Glass Works v. Sumitomo Electric, 9 U.S.P.Q.2d 1962, 1965 (Fed. Cir. 1989). The exclusion of a claimed element, no matter how insubstantial or obvious, from a reference is enough to negate anticipation. Connell v. Sears, Roebuck & Co., 220 U.S.P.Q 193, 1098 (Fed. Cir. 1983). Applicants respectfully submit that Yguerabide cannot be applied to support an anticipation rejection of the claims under 35 U.S.C. section 102(e).

Yguerabide relates to the use of metallic nanoparticles in detection methods based on light scattering. While Yguerabide does describe the use of particular gold nanoparticles for nucleic acid detection, see Example 32 (col. 110), Yguerabide does not disclose or suggest any nanoparticle whereby "in the presence of the nucleic acid target and under hybridization conditions, the nanoparticles having oligonucleotides bound thereto form a complex with the nucleic acid target, the resulting complex having a sharp melting profile and increased melting temperature relative to a comparable complex without nanoparticles, to allow for selective discrimination of any nucleotide insertion, deletion, or mismatch in the nucleic acid target." See, for instance, present claim 2. Yguerabide is completely silent with respect to any nanoparticle that is capable for forming a complex with a target nucleic acid whereby the complex has a sharp melting profile and increased melting temperature. Moreover, Yguerabide is completely silent with respect to a detection system that employs at least one metallic or semiconductor nanoparticle labeled with a fluorescent molecule (e.g., claim 113) or at least a first type and a second type of metallic or semiconductor nanoparticles (e.g., claim 42) labeled with fluorescent molecules. In the presence of a nucleic acid target, the detection probes moves from a quenched to unquenched state and leads to fluorescence changes. Withdrawal of the section 102(e) rejection based on Yguerabide is in order and is respectfully requested. Furthermore, Yguerabide cannot be used to reject the claims as being unpatentable under 35 U.S.C. section 103.

The Federal Circuit reiterated the manner in which obviousness rejections are to be reviewed. Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, "a proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success." *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991), citing *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 U.S.P.Q. 2d 1529, 1531 (Fed. Cir. 1988). As the Federal Circuit emphasized by succinctly summarizing: "Both the suggestion and the reasonable expectation of success must be founded in the prior art, not

in the Applicants' disclosure." *Id.* Contrary to the Examiner's position, Applicants respectfully submit that Yguerabide does not suggest doing what the Applicants have done.

The Applicant respectfully submits that Yguerabide does not suggest anywhere nanoparticle-oligonucleotide conjugate probes having sharp melting profiles, increased melting temperatures, and extraordinary discrimination properties. The nanoparticle-labeled probes of the invention that form complexes with target nucleic acids have sharp melting profiles and increased melting temperatures which is both surprising and unexpected since this property allows for extraordinary discrimination between perfectly matched and mismatched nucleic acid targets relative to complexes not having nanoparticles. For instance, as shown in Figure 12 and discussed in Example 5 (page 90 in the specification), nanoparticle labeled oligonucleotide probes were prepared and contacted with various target nucleic acids under stringent conditions. With fully matched targets, the complex produced a positive result (blue color); with targets having one mismatched base, no complex formation occurred with the probes. Yguerabide is completely silent with respect to any nanoparticle-oligonucleotide probe whereby "in the presence of the nucleic acid target and under hybridization conditions, the nanoparticles having oligonucleotides bound thereto form a complex with said nucleic acid, the resulting complex having a sharp melting profile and increased melting temperature relative to a comparable complex without nanoparticles, to allow for selective discrimination of any nucleotide insertion, deletion, or mismatch in the nucleic acid target." Furthermore, Yguerabide is completely silent with respect to a detection system that employs at least one metallic or semiconductor nanoparticle labeled with a fluorescent molecule (e.g., claim 113) or at least a first type and a second type of metallic or semiconductor nanoparticles (e.g., claim 42) labeled with fluorescent molecules. See, for instance, Figure 20A and the specification at page 25, lines 10-12 and page 51. line 28 to page 54, line 29, which illustrates fluorescent-labeled oligonucleotides attached to metallic or semiconductor quenching nanoparticles. Accordingly, withdrawal of the section 103(a) rejection against the claims based on Yguerabide is in order and is respectfully requested.

Reconsideration of this application and a favorable determination is respectfully requested. The Examiner is invited to contact the undersigned if the Examiner believes that this would be helpful in expediting the prosecution of this application.

Respectfully submitted,

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APPENDIX A (Clean copy of all pending claims)

2. (Amended) A method of detecting a nucleic acid target having at least two portions, said method comprising:

contacting the nucleic acid target with at least two types of nanoparticles having oligonucleotides attached thereto, the oligonucleotides on the first type of nanoparticles having a sequence complementary to a first portion of the sequence of the nucleic acid target, the oligonucleotides on the second type of nanoparticles having a sequence complementary to a second portion of the sequence of the nucleic acid target, the contacting taking place under conditions effective to allow hybridization of the oligonucleotides on the nanoparticles with the nucleic acid target, wherein in the presence of the nucleic acid target and under hybridization conditions, the nanoparticles having oligonucleotides bound thereto form a complex with the nucleic acid target, the resulting complex having a sharp melting profile and increased melting temperature relative to a comparable complex without nanoparticles, to allow for selective discrimination of any nucleotide insertion, deletion, or mismatch in the nucleic acid target; and

observing a detectable change brought about by hybridization of the oligonucleotides on the nanoparticles with the nucleic acid target.

3. (Original) The method of Claim 2 wherein the contacting conditions include freezing and thawing.

4. (Original) The method of Claim 2 wherein the contacting conditions include heating.

5. (Original) The method of Claim 2 wherein the detectable change is observed on a solid surface.

6. (Original) The method of Claim 2 wherein the detectable change is a color change observable with the naked eye.

7. (Original) The method of Claim 6 wherein the color change is observed on a solid surface.

8. (Original) The method of Claim 2 wherein the nanoparticles are made of gold.

9. (Amended) The method of Claim 2 wherein the oligonucleotides attached to the nanoparticles are labeled on their ends not attached to the nanoparticles with molecules that produce a detectable change upon hybridization of the oligonucleotides on the nanoparticles with the nucleic acid target.

10. (Original) The method of Claim 9 wherein the nanoparticles are metallic or semiconductor nanoparticles and the oligonucleotides attached to the nanoparticles are labeled with fluorescent molecules.

11. (Amended) The method of Claim 2 wherein:

the nucleic acid target has a third portion located between the first and second portions, and the sequences of the oligonucleotides on the nanoparticles do not include sequences complementary to this third portion of the nucleic acid target; and

the nucleic acid target is further contacted with a filler oligonucleotide having a sequence complementary to this third portion of the nucleic acid target, the contacting taking place under conditions effective to allow hybridization of the filler oligonucleotide with nucleic acid target.

12. (Amended) The method of Claim 2 wherein the nucleic acid target is viral RNA or DNA.

13. (Amended) The method of Claim 2 wherein the nucleic acid target is a gene associated with a disease.

14. (Amended) The method of Claim 2 wherein the nucleic acid target is a bacterial DNA.

15. (Amended) The method of Claim 2 wherein the nucleic acid target is a fungal DNA.

16. (Amended) The method of Claim 2 wherein the nucleic acid target is a synthetic DNA, a synthetic RNA, a structurally-modified natural or synthetic RNA, or a structurally-modified natural or synthetic DNA.

17. (Amended) The method of Claim 2 wherein the nucleic acid target is from a biological source.

A4

18. (Amended) The method of Claim 2 wherein the nucleic acid target is a product of a polymerase chain reaction amplification.

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19. (Amended) The method of Claim 2 wherein the nucleic acid target is contacted with the first and second types of nanoparticles simultaneously.

20. (Amended) The method of Claim 2 wherein the nucleic acid target is contacted and hybridized with the oligonucleotides on the first type of nanoparticles before being contacted with the second type of nanoparticles.

21. (Original) The method of Claim 20 wherein the first type of nanoparticles is attached to a substrate.

22. (Amended) The method of Claim 2 wherein the nucleic acid target is double-stranded and hybridization with the oligonucleotides on the nanoparticles results in the production of a triple-stranded complex.

23. (Amended) A method of detecting nucleic acid target having at least two portions comprising:

A5

providing a substrate having a first type of nanoparticles attached thereto, the nanoparticles having oligonucleotides attached thereto, the oligonucleotides having a sequence complementary to a first portion of the sequence of the nucleic acid target;

contacting the nucleic acid target with the nanoparticles attached to the substrate under conditions effective to allow hybridization of the oligonucleotides on the second type of nanoparticles with the nucleic acid target;

providing a second type of nanoparticles having oligonucleotides attached thereto, the oligonucleotides having a sequence complementary to one or more other portions of the sequence of the nucleic acid target;

contacting the nucleic acid bound to the substrate with the second type of nanoparticles under conditions effective to allow hybridization of the oligonucleotides on the second type of nanoparticles with the nucleic acid target; and

observing a detectable change, wherein in the presence of the nucleic acid target and under hybridization conditions, the nanoparticles having oligonucleotides bound thereto form a complex with the nucleic acid target, the resulting complex having a sharp melting profile and increased melting temperature relative to a comparable complex without nanoparticles, to allow for selective discrimination of any nucleotide insertion, deletion, or mismatch in the nucleic acid target.

24. (Original) The method of Claim 23 wherein the nanoparticles are made of gold.

29. (Amended) A method of detecting a nucleic target acid having at least two portions, said method comprising:

contacting the nucleic acid target with a substrate having oligonucleotides attached thereto, the oligonucleotides having a sequence complementary to a first portion of the sequence of the nucleic acid target, the contacting taking place under conditions effective to allow hybridization of the oligonucleotides on the substrate with the nucleic acid target;

contacting the nucleic acid target bound to the substrate with a first type of nanoparticles having oligonucleotides attached thereto, the oligonucleotides having a sequence complementary to one or more other portions of the sequence of the nucleic acid target, the contacting taking place under conditions effective to allow hybridization of the oligonucleotides on the nanoparticles with the nucleic acid target;

contacting the first type of nanoparticles bound to the substrate with a second type of nanoparticles having oligonucleotides attached thereto, the oligonucleotides on the second type of nanoparticles having a sequence complementary to at least a portion of the sequence of the oligonucleotides on the first type of nanoparticles, the contacting taking place under conditions effective to allow hybridization of the oligonucleotides on the first and second types of nanoparticles; and

observing a detectable change, wherein in the presence of the nucleic acid target and under hybridization conditions, the nanoparticles having oligonucleotides bound thereto form a complex with the nucleic acid target, the resulting complex having a sharp melting profile and increased melting temperature relative to a comparable complex without nanoparticles, to allow for selective discrimination of any nucleotide insertion, deletion, or mismatch in the nucleic acid target.

30. (Original) The method of Claim 29 wherein the substrate is transparent.

31. (Original) The method of Claim 30 wherein the detectable change is the formation of dark areas on the substrate.

32. (Original) The method of Claim 29 wherein the nanoparticles are made of gold.

42. (Amended) A method of detecting a nucleic acid target having at least two portions comprising:

providing a first type of metallic or semiconductor nanoparticles having oligonucleotides attached thereto, the oligonucleotides having a sequence complementary to a first portion of the sequence of the nucleic acid target and being labeled with a fluorescent molecule;

providing a second type of metallic or semiconductor nanoparticles having oligonucleotides attached thereto, the oligonucleotides having a sequence complementary to a second portion of the sequence of the nucleic acid target and being labeled with a fluorescent molecule;

A7

contacting the nucleic acid target with the two types of nanoparticles under conditions effective to allow hybridization of the oligonucleotides on the two types of nanoparticles with the nucleic acid target; and

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observing changes in fluorescence.

43. (Original) The method of Claim 42 further comprising placing a portion of the mixture of the nanoparticles and the nucleic acid target in an observation area located on a microporous material, treating the microporous material so as to remove any unbound nanoparticles from the observation area, and then observing the changes in fluorescence.

106. (New) The method of Claim 42, wherein in the presence of the nucleic acid target and under hybridization conditions, the nanoparticles having oligonucleotides bound thereto form a complex with the nucleic acid target, the resulting complex having a sharp melting profile and increased melting temperature relative to a comparable complex without nanoparticles, to allow for selective discrimination of any nucleotide insertion, deletion, or mismatch in the nucleic acid target.

A8

107. (New) The method of claim 42 wherein the nucleic acid target is contacted and hybridized with the oligonucleotides on first type of nanoparticles before being contacted with the second type of nanoparticles.

108. (New) The method of claim 42 wherein the nucleic acid target is contacted and hybridized with the oligonucleotides on second type of nanoparticles before being contacted with the first type of nanoparticles.

109. (New) The method of claim 42 wherein the nucleic acid target is simultaneously contacted with the first and second types of nanoparticles.

110. (New) The method of claim 42 wherein the fluorescent molecule bound to the oligonucleotides of the first type of nanoparticles is a donor and the fluorescent molecule bound to the oligonucleotides of the second type of nanoparticles is an acceptor.

112. (New) The method of claim 42 wherein the fluorescent molecule bound to the oligonucleotides of the first type of nanoparticles is an acceptor and the fluorescent molecule bound to the oligonucleotides of the second type of nanoparticles is a donor.

113. (New) A method of detecting a nucleic acid target having one or more portions, said method comprising:

providing at least one type of metallic or semiconductor nanoparticles having oligonucleotides attached thereto, the oligonucleotides having a sequence complementary to at least one portion of the sequence of the nucleic acid target and being labeled with a fluorescent molecule;

A8

contacting the nucleic acid target with at least one type of nanoparticles under conditions effective to allow hybridization of the oligonucleotides on the nanoparticles with the nucleic acid target; and

observing changes in fluorescence.

Cont

114. (New) The method according to claim 113, further comprising providing a second type of metallic or semiconductor nanoparticles having oligonucleotides attached thereto, the oligonucleotides having a sequence complementary to at least one other portion of the sequence of the nucleic acid target and being labeled with a fluorescent molecule.

115. (New) The method according to claim 114, further comprising contacting the nucleic acid target with the second type of nanoparticles under conditions effective to allow hybridization of the oligonucleotides on the nanoparticles with the nucleic acid target.

116. (New) The method of claim 115 wherein the nucleic acid target is contacted and hybridized with the oligonucleotides on first type of nanoparticles before being contacted with the second type of nanoparticles.

117. (New) The method of claim 115 wherein the nucleic acid target is contacted and hybridized with the oligonucleotides on second type of nanoparticles before being contacted with the first type of nanoparticles.

118. (New) The method of claim 115 wherein the nucleic acid target is simultaneously contacted with the first and second types of nanoparticles.

A8

119. (New) The method of claim 115 wherein the fluorescent molecule bound to the oligonucleotides of the first type of nanoparticles is a donor and the fluorescent molecule bound to the oligonucleotides of the second type of nanoparticles is an acceptor.

CONT.

120. (New) The method of claim 115 wherein the fluorescent molecule bound to the oligonucleotides of the first type of nanoparticles is an acceptor and the fluorescent molecule bound to the oligonucleotides of the second type of nanoparticles is a donor.

121. (New) The method of Claim 113, wherein in the presence of the nucleic acid target and under hybridization conditions, the nanoparticles having oligonucleotides bound thereto form a complex with the nucleic acid target, the resulting complex having a sharp melting profile and increased melting temperature relative to a comparable complex without nanoparticles, to allow for selective discrimination of any nucleotide insertion, deletion, or mismatch in the nucleic acid target.

APPENDIX B

ATTY Case No.	Serial No./ Filing Date	Inventors/Title	Status
00-653-A	U.S. 09/927,777 Filed 8/10/01	Mirkin, Letsinger, Mucic, Storhoff, Elghanian, Taton, Garamella, Li, Park/ NANOPARTICLES HAVING OLIGONUCLEOTIDES ATTACHED THERETO AND USES THEREFORE	PENDING
00-713-B1	09/923,625 Filed 8/7/01	Mirkin, Letsinger, Mucic, Storhoff, Elghanian/ NANOPARTICLES HAVING OLIGONUCLEOTIDES ATTACHED THERETO AND USES THEREFOR	PENDING
00-713-C	09/344,667, filed 6/25/99	Mirkin, Letsinger, Mucic, Storhoff, Elghanian/ NANOPARTICLES HAVING OLIGONUCLEOTIDES ATTACHED THERETO AND USES THEREFORE	U.S. Patent No. 6,361,944, issued 3/26/02
00-713-I	U.S.S.N 09/603,830 Filed 6/26/00	Mirkin, Letsinger, Mucic, Storhoff, Elghanian, Taton; NANOPARTICLES HAVING OLIGONUCLEOTIDES ATTACHED THERETO AND USES THEREFOR	U.S. Patent No. 6,506,564, issued 1/14/03
00-713-I-1	09/961,949 9/20/01	Mirkin, Letsinger, Mucic, Storhoff, Elghanian, Taton;	ALLOWED

ATTY Case No.	Serial No./ Filing Date	Inventors/Title	Status
		NANOPARTICLES HAVING OLIGONUCLEOTIDES ATTACHED THERETO AND USES THEREFOR	
00-713-I-2	09/957,318 9/20/01	See 00-713-I-1	PENDING
00-713-I-3	09/957,313 9/20/01	See 00-713-I-1	ALLOWED
00-713-I-4	09/966,491 9/28/01	See 00-713-I-1	ALLOWED
00-713-I-5	09/966,312 9/28/01	See 00-713-I-1	PENDING
00-713-I-6	09/967,409 9/28/01	See 00-713-I-1	PENDING
00-713-I-7	09/974,500 10/10/01	See 00-713-I-1	PENDING
00-713-I-8	09/974,007 10/10/01	See 00-713-I-1	PENDING
00-713-I-9	09/973,638 10/10/01	See 00-713-I-1	PENDING
00-713-I-10	09/973,788 10/10/01	See 00-713-I-1	PENDING
00-713-I-11	09/975,062 10/11/01	See 00-713-I-1	PENDING
00-713-I-12	09/975,376 10/11/01	See 00-713-I-1	PENDING
00-713-I-13	09/975,384 10/11/01	See 00-713-I-1	PENDING
00-713-I-14	09/975,498 10/11/01	See 00-713-I-1	ALLOWED

ATTY Case No.	Serial No./ Filing Date	Inventors/Title	Status
00-713-I-15	09/975,059 11/11/01	See 00-713-I-1	PENDING
00-713-I-16	09/976,601 10/12/01	See 00-713-I-1	PENDING
00-713-I-17	09/976,968 10/12/01	See 00-713-I-1	PENDING
00-713-I-18	09/976,971 10/12/01	See 00-713-I-1	PENDING
00-713-I-19	09/976,863 10/12/01	See 00-713-I-1	PENDING
00-713-I-20	09/976,577 10/12/01	See 00-713-I-1	PENDING
00-713-I-21	09/976,618 10/12/01	See 00-713-I-1	PENDING
00-713-I-22	09/981,344 10/15/01	See 00-713-I-1	PENDING
00-713-I-23	09/976,900 10/12/01	See 00-713-I-1	PENDING
00-713-I-24	09/976,617 10/12/01	See 00-713-I-1	PENDING
00-713-I-25	09/976,378 10/12/01	See 00-713-I-1	PENDING
00-713-i-26	TBA 041003	See 00-713-I-1	PENDING
00-713-L	U.S.S.N. 09/693,005 Filed 10/20/00	Mirkin, Letsinger, Mucic, Storhoff, Elghanian/ NANOPARTICLES HAVING OLIGONUCLEOTIDES ATTACHED THERETO AND	U.S. Patent No. 6,495,324, issued 12/17/02

ATTY Case No.	Serial No./ Filing Date	Inventors/Title	Status
		USES THEREFORE	
00-713-M	U.S.S.N. 09/693,352 Filed 10/20/00	Mirkin, Letsinger, Mucic, Storhoff, Elghanian/ NANOPARTICLES HAVING OLIGONUCLEOTIDES ATTACHED THERETO AND USES THEREFORE	U.S. Patent No. 6,417,340, issued 7/9/02
00-714-G	U.S. 09/830,620 Filed 8/15/01	Mirkin, Nguyen/ NANOPARTICLES WITH POLYMER SHELLS	PENDING
00-715-A	U.S. 09/760,500 Filed 1/12/01	Mirkin, Letsinger, Mucic, Storhoff, Elghanian, Taton; Garamella, Li/ METHOD OF ATTACHING OLIGONUCLEOTIDES TO NANOPARTICLES AND PRODUCTS PRODUCED THEREBY	PENDING
00-1085-A	U.S.S.N. 09/820,279 Filed 3/28/01	Mirkin,Letsinger, etc./ METHOD AND MATERIALS FOR ASSAYING BIOLOGICAL MATERIALS	PENDING
00-1086-A	U.S. 09/903,461 Filed 7/11/01	Letsinger, Garimella/ METHOD OF DETECTION BY ENHANCEMENT OF SILVER STAINING	ALLOWED
01-565-A	USSN 10/125,194 Filed 4/18/02	Mirkin, Nguygen, Watson, Park/ OLIGONUCLEOTIDE-MODIFIED ROMP POLYMERS AND CO-	PENDING

ATTY Case No.	Serial No./ Filing Date	Inventors/Title	Status
		POLYMERS	
01-599-A	U.S.S.N. 10/291,291 Filed 11/08/02	Storhoff/NOVEL THIOL-BASED METHOD FOR ATTACHING OLIGONUCLEOTIDES TO NANOPARTICLES	PENDING
01-661-A	U.S.S.N. 10/034,451 Filed 12/28/01	Mirkin, Cao, Jin/ DNA-MODIFIED CORE-SHELL AG/AU NANOCRYSTALS	PENDING
01-661-C	U.S.S.N. 10/153,483 Filed 5/22/02	Mirkin, Cao, Jin/ DNA-MODIFIED CORE-SHELL AG/AU NANOCRYSTALS	PENDING
01-1565-A	U.S.S.N. 10/266,983 Filed 10/08/02	Park, Taton, Mirkin/ARRAY-BASED ELECTRICAL DETECTION OF DNA USING NANOPARTICLE PROBES	PENDING
01-1705-A	U.S.S.N. 10/108,211 Filed 3/27/02	Nam, Park, Mirkin/BIO-BARCODES BASED ON OLIGONUCLEOTIDE-MODIFIED NANOPARTICLES	PENDING
02-338-B	USSN 10/172,428 Filed 6/14/02	Cao, Jin, Nam, Mirkin/MULTICHANNEL DETECTION USING NANOPARTICLE PROBES WITH RAMAN SPECTROSCOPIC FINGERPRINTS	PENDING